HIVOX®

HIVOX BIOTEK INC.
5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan
Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

5. 510(k) SUMMARY (According to 21 CFR 807.92)

● 510(K) OWNER'S NAME	HIVOX BIOTEK INC. 5F, No.123, Shingde Road, Sanchong Dist., New Taipei City, 24158, TAIWAN, R.O.C. TEL: +886-2-85112668 FAX:+886-2-85112669
● Contact Person	Dr. JEN, KE-MIN TEL: 886-2-85112668 FAX:886-3-5209783 Email: ceirs.jen@msa.hinet.net
● Date of Submission:	May 23, 2014
● Trade Name	HIVOX Electric Stimulator OTC TENS, *Rapid Relief*™ Pennypad PP-904
● Predicate Devices	K112392 HIVOX Electric Stimulator OTC TENS, Pennypad 904, 907, and 909
● Common Name	Electric Stimulator OTC TENS
● Classification Name	Stimulator, Nerve, Transcutaneous, Over-The-Counter (21 CFR 890.5890, Product Code NUH)
● Panel	Neurology
● Intended Use	The HIVOX Electric Stimulator OTC TENS, *Rapid Relief* ™ Pennypad PP-904, is indicated for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg), and lower back due to strain from exercise or normal household and work activities.
● Device Design	The HIVOX Electric Stimulator OTC TENS, *Rapid Relief* ™ Pennypad PP-904, can generate small pulses of electrical current and delivered these pulses pass through the skin and activated underlying nerves.

Product Specifications:

Power CR2032 x 1

Pulse rate : 2, 5, and 40Hz (Fixed)

Pulse width: 200μS(fixed)

Electric impedance of the device: 4.80~5.20 Mohms

Output voltage Max. : 57.6 Vp-p, based on 500 Ohm load ± 10%

Treatment time: 20 minutes fixed

Pulse strength: 0 ~ 15 stages adjustable

Operation environment :10 ~ 40° C, 30 ~ 85% RH

Storage environment: -10 ~ 50° C, 10 ~ 95% RH

Transport environment: -10 ~ 50° C, 35 ~ 85% RH

Size: 113 x 70 x 10 mm

Applicable Electrical Range for the Electrode Pads:

Pulse rate: 1~150 Hz

Pulse strength: 1~150 V

Pulse width: 100μS ~ 500 mS

- Performance Tests Submitted:

The relevant standards including:

1. IEC/EN 60601-1 : Medical electrical equipment Part 1. General requirements for safety, 1996.
2. IEC/EN 60601-1-2 : Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2007.
3. IEC/EN 60601-2-10 : Medical electrical equipment, Part 2-10: Particular requirements for safety of nerve and muscle stimulators, 2001.

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Compared to Legally Marketed Predicate Devices

Parameter			HIVOX (K112392)			HIVOX Subject Device
Mode or Program Name			PP909	PP907	PP904	*Rapid Relief*™ Pennypad PP-904
Indication for Applied Area for pain relieve			Lower Back	Arm and Leg	Lower Back	Arm, Leg, and Lower Back
dimensions			113L * 70W * 9.7H mm			
Waveform			Symmetrical Biphasic			
Shape			Rectangular			
Maximum Output Voltage (Volts) (±20%)		@500Ω	40.0Vpp	68.8V	57.6Vpp	
		@2KΩ	84.0Vpp	88.0V	89.6Vpp	
		@10KΩ	92.0Vpp	95.2V	96.0Vpp	
Maximum Output Current(±20%)		@500Ω	80.0mApp	137.6mA	115.2mApp	
		@2KΩ	42.0mApp	44.0mA	44.8mApp	
		@10KΩ	9.2mApp	9.52mA	9.6mApp	
Duration of primary (depolarizing) phase (μSec)			NA			
Pulse Duration (μSec)			200μSec (fixed)			
Frequency (Hz)			35	2 and 40	2, 5, and 40	
Net Charge (μC) per pulse		@500Ω	0.3200	1.1008	0.2304	
Maximum Charge (μC)		@500Ω	16.0	27.52	23.04	
Maximum Current Density (mA/cm^2, r.m.s.)		@500Ω	1.964	3.378	2.828	
Maximum Average Power Density (W/cm^2)		@500Ω	0.078	0.232	0.163	
Burst Mode	a. Pulse per burst		1	NA	NA	
	b. Burst per second		4	NA	NA	
	c. Burst duration (sec)		2	NA	NA	
	d. Duty Cycle		8	NA	NA	
ON Time(sec)			120			
Off Time(sec)			0			
Additional Features			NA			

Note: Only the subject device Pennypad 909 has the "Burst Mode".

DISCUSSION:

The predicate devices, HIVOX Electric Stimulator OTC TENS, Pennypad 904, Pennypad 907, and Pennypad 909, have the same visional appearance, software, and dimensions (113 * 70 * 9.7 mm) as the subject device.

The main differences among the predicated devices are the Indication for Applied Area for pain relieve,,

- Pennypad -904 and Pennypad 909 OTC TENS – Lower Back pain relieve
- Pennypad 907 OTC TENS – Arm and Leg pain relieve
- Only Pennypad 909 has the "Burst Mode".

The subject device, HIVOX Electric Stimulator OTC TENS, *Rapid Relief*™ Pennypad PP-904, is identical to the predicate devices and only extends the Indication for Applied Area for pain relieve to include the Arm and Leg pain relief.

CONCLUSION:

The subject device, HIVOX Electric Stimulator OTC TENS *Rapid Relief* ™ Pennypad PP-904, applied for the Arm, Leg, and Lower Back pain relieve is as safe and effective as, and functions in a manner equivalent to the predicate devices. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2014

HIVOX BIOTEK INC.
Dr. Jen, Ke-Min
8F, No. 98, Shingde Road, Sanchong District,
Taipei City, Taiwan, ROC

Re: K140650
Trade/Device Name: Pennypad 904
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NUH
Dated: May 24, 2014
Received: May 30, 2014

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below

510(k) Number (if known)

K140650

Device Name

HIVOX Electric Stimulator OTC TENS, *Rapid Relief*™ Pennypad PP-904

Indications for Use (*Describe*)

The *Rapid Relief*™ Pennypad PP-904 is indicated for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg), and lower back due to strain from exercise or normal household and work activities.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

Felipe Aguel -S

Date: 2014.06.27 16:33:16 -04'00'

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